REMARKS

Please reconsider this application in view of the above amendments and the following remarks.

- Claims 1, 2, 5, 9-13, 15-18, 20-22, 24-34, and 36-44 are pending.
- Claims 1, 2, 5, 9-13, 15-18, 20-22, 24-34, and 36-44 are rejected.
- Claim 35 is withdrawn as nonelected.

Applicants have amended to claims, as shown above.

Applicants have amended Claims 1, 5, 22, 41, 42, 43, and 44 to explicitly recite steps that were previously inherent in the claims. Applicants have amended Claims 20, 21, 30, and 33 to conform their language to that of their amended parent claims.

Applicants have amended Claims 11-13, 15, 16, 25, 28, 32, and 34 to conform their punctuation usage to that of the remainder of the claims.

None of these claim amendments adds new matter.

Art-based Rejections

The Examiner has maintained the rejection of claims 1 and 41 under 35 USC 102(b) in view of Pursley.

Applicants traverse this rejection because Pursley does not teach each and every element of Claims 1 or 41.

Applicants teach applying a dissolved polymer to a heated implantable medical device in these claims. Pursley does not teach applying a dissolved polymer to a heated implantable medical device. While Pursley mentions in passing the use of a solvenated

polymer, all of the discussion and the examples in Pursley relate to applying a solid polymer. Therefore, Pursley as a whole teaches depositing solid polymer onto a mandrel.

Furthermore, Applicants have been unable to document that the term "solvenated polymer" means a dissolved polymer. "Solvenated" was investigated in several general and technical dictionaries, on the Web generally, and published US patents were searched for the terms "solvenated" and "polymer". This investigation did not show that one of ordinary skill in the art at the time the Pursley patent was filed understood solvenated polymer to mean dissolved polymer.

Since it is the Examiner's responsibility in preparing a prima facie case of anticipation to show that each and every element of the claimed invention is disclosed in the prior art reference, Applicants request documentation showing that one of ordinary skill in the art viewing the term "solvenated polymer" would expect it to mean a dissolved polymer. If the Examiner wishes to take official notice of the definition of solvenated polymer, of course the Examiner may do so. M.P.E.P. § 2144.03 states that "the rationale for supporting an obviousness rejection may be based on common knowledge in the art or 'well-known' prior art" and the "examiner may take official notice of facts outside of the record which are ***capable of instant and unquestionable demonstration*** as being 'well-known' in the art." If an applicant traverses such an assertion, the Examiner is required to cite a reference in support of her position.

Applicants traverse that assertion and ask for such a reference.

Claims 1 and 41, as amended, also teach that the step of providing a medical device capable of being implanted precedes providing a coating substance. Pursley's catheter liner is incapable of being implanted until after it is turned into a catheter. Pursley does not teach or envision implanting its catheter liner absent a polymer coating. Therefore, Pursley is not an anticipatory reference.

Please remove this rejection based on 35 USC 102(b).

The Examiner rejects claims 5, 9-13, 22, 26-27, 29, 33, 34, and 37-40 under 35 USC 103(a) as being unpatentable over Fan et al.

Applicants previously asserted that the Fan reference does not teach spraying a polymer solution. Upon closer inspection of Fan, Applicants realize that that assertion was incorrect and apologize for any confusion this error has caused.[1]

Fan teaches that its polymer coating must contain a polyisocyanate and must contain polyethylene oxide.[2] Fan posits that its polymer coating's excellent performance comes from the chemical interaction of polyethylene oxide and the in-situ hydrolysis products of the polyisocyanate.[3]

Fan teaches a mode of action different from that of the instant application. Therefore, Fan cannot make the instant claims obvious. Moreover, Fan specifically teaches away from multiple coating steps, which Claim 5 requires.[4] Because Fan teaches single coatings, one of ordinary skill in the art would not start with the teachings of Fan to arrive at Applicants claimed invention. Also, since Fan teaches away from multiple coatings, combining Fan's teachings with prior art teachings of polymer coatings with multiple layers is improper.

Accordingly, the Examiner has failed to make out a prima-facie obviousness case for these claims.

Please promptly remove this obviousness-based rejection.

Since the Examiner has not made out prima facie obviousness with this reference combination because the Examiner has not explained how this combination makes the parent claim(s) obvious, the current rejection of the dependent claims is moot. But Applicants do not acquiesce to the Examiner's various arguments in the rejections of subgroups of the dependent claims and reserve the right to deal with the specifics of the rejections in the future, if that becomes necessary.

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[1] See Fan, column 4, line 34.
[2] See Fan, column 3, line 1; and Fan, column 2, line 44, respectively.

The Examiner has rejected claims 9-10, 15-18, and 20 under 35 USC 103(a) as being unpatentable over Fan in view of Zhong.

Fan teaches that its polymer coating must contain a polyisocyanate and must contain polyethylene oxide.[5] Fan posits that its polymer coating's excellent performance comes from the chemical interaction of polyethylene oxide and the in-situ hydrolysis products of the polyisocyanate.[6]

Since Fan requires a polyisocyanate and a polyethylene oxide, it teaches away from a combination with Zhong because Zhong contains no such requirements and generally teaches a wide range of polymers as being suitable. Also, since one of ordinary skill in the art would expect the mode of action in Fan to require the chemical interaction of polyethylene oxide and the in situ hydrolysis products of the polyisocyanate, that artisan would not have substituted Zhong's polymers into Fan because the artisan would not expect Zhong's polymers to have the requisite chemical interactions. Substituting Zhong's polymers into the invention of Fan would change the mode of action described in Fan. Therefore, Fan cannot make the instant claims obvious.

Please promptly remove this obviousness-based rejection.

Accordingly, the Examiner has failed to make out a prima-facie obviousness case for these claims. Please promptly remove this obviousness-based rejection.

Since the Examiner has not made out prima facie obviousness with this reference combination because the Examiner has not explained how this combination makes the parent claim(s) obvious, the current rejection of the dependent claims is moot. But Applicants do not acquiesce to the Examiner's various arguments in the rejections of subgroups of the dependent claims and reserve the right to deal with the specifics of the rejections in the future, if that becomes necessary.

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[3] See Fan, column 3, line 64, through column 4, line 2.
[4] Column 15, line 64, and column 3, line 55-60.
[5] See Fan, column 3, line 1; and Fan, column 2, line 44, respectively.
[6] See Fan, column 3, line 64, through column 4, line 2.

The Examiner has rejected Claims 21, 30, 31, 43, and 44 under 35 USC 103(a) as being unpatentable over Fan in view of Pursley.

Fan teaches that its polymer coating must contain a polyisocyanate and must contain polyethylene oxide.[7] Fan posits that its polymer coating's excellent performance comes from the chemical interaction of polyethylene oxide and the in-situ hydrolysis products of the polyisocyanate.[8]

Since Fan requires a polyisocyanate and a polyethylene oxide, it teaches away from a combination with Pursley because Pursley contains no such requirements. Moreover, Pursley teaches that any of a variety of polymers is useful in its invention. Also, since one of ordinary skill in the art would expect the mode of action in Fan to require the chemical interaction of polyethylene oxide and the in situ hydrolysis products of the polyisocyanate, that artisan would not have substituted Pursley's polymers because the artisan would not expect Pursley's polymers to have the requisite chemical interactions. Substituting Pursley's polymers into the invention of Fan would change the mode of action described in Fan. Therefore, Fan cannot make the instant claims obvious.

Accordingly, the Examiner has failed to make out a prima-facie-obviousness case for these claims. Please promptly remove this obviousness-based rejection.

Furthermore, as discussed above, Pursley fails to teach a polymer solution and fails to teach providing a preheated implantable medical device followed by coating that medical device with the polymer solution. Therefore, the combination of Pursley with Fan fails to teach or suggest all of the limitations of these claims. For instance, the cited combination does not teach applying a polymer solution to a preheated implantable medical device.

Please promptly remove this obviousness-based rejection.

Since the Examiner has not made out prima facie obviousness with this reference combination because the Examiner has not explained how this combination makes the

[7] See Fan, column 3, line 1; and Fan, column 2, line 44, respectively.

parent claim(s) obvious, the current rejections of the dependent claims are moot. But Applicants do not acquiesce to the Examiner's position in the rejections of sub-groups of the dependent claims and reserve the right to deal with the specifics of the rejections in the future, if that becomes necessary.

The Examiner has rejected Claims 28 and 32 under 35 USC 103(a) as being unpatentable over Fan in view of Whitbourne.

Fan teaches that its polymer coating must contain a polyisocyanate and must contain polyethylene oxide.[9] Fan posits that its polymer coating's excellent performance comes from the chemical interaction of polyethylene oxide and the in-situ hydrolysis products of the polyisocyanate.[10]

Assuming Whitbourne teaches the equivalence of poly-n-butyl methacrylate and isocyanates, Fan's invention requires and teaches that it requires isocyanates. Therefore, Fan teaches that poly n-butyl methacrylate and isocyanates are NOT equivalent in its invention. The combination of Whitbourne and Fan would not motivate one of ordinary skill in the art to substitute poly-n-butyl methacrylate for an isocyanate because Fan teaches away from substituting any other polymer for an isocyanate in its invention.

Accordingly, the Examiner has failed to make out a prima-facie-obviousness case for these claims.

Please promptly remove this obviousness-based rejection.

The Examiner has rejected Claims 25 under 35 USC 103(a) as being unpatentable over Pursley in view of Whitbourne

Applicants teach applying a dissolved polymer to a heated implantable medical device in these claims. Pursley does not teach applying a dissolved polymer to a heated

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[8] See Fan, column 3, line 64, through column 4, line 2.
[9] See Fan, column 3, line 1; and Fan, column 2, line 44, respectively.
[10] See Fan, column 3, line 64, through column 4, line 2.

implantable medical device. While Pursley mentions in passing the use of a solvenated polymer, all of the discussion in examples in Pursley relate to applying a solid polymer.

Furthermore, as discussed above, Applicants have been unable to document that the term "solvenated polymer" means a dissolved polymer.

Since it is the Examiner's responsibility in preparing a prima facie case of obviousness to show that each and every element of the claimed invention is taught by the combination, Applicants request documentation that one of ordinary skill in the would view the term "solvenated polymer" as meaning in dissolved polymer.

Claim 25 percent as the step of providing a medical device capable of being implanted precedes providing a coating substance. Pursley's catheter liner is incapable of being implanted until after it is turned into a catheter. Pursley does not teach or envision implanting its catheter liner absent a polymer coating. The Examiner has not explained why one of ordinary skill in the art would be motivated to substitute an implantable medical device for the catheter liner disclosed by Pursley. Whitbourne, for instance, does not supply that motivation.

Accordingly, the Examiner has failed to make out a prima-facie-obviousness case for this claim.

Please promptly remove this obviousness-based rejection.

The Examiner has rejected claims 5, 11-13, and 27 under 35 USC 103(a) as being unpatentable over Ofstead.

On page 10 of the instant office action, the examiner states the following:

> Time savings is a significant benefit of skipping or repeating a dry step. A decrease in production time would yield greater profits. And, based on the teachings of Ofstead, limitation of the step may indeed produce inferior results, however there is a range of acceptable results in industry. The loss of some degree of quality for a large savings in

> time is a decision that one of ordinary skill in the art would be capable of making.

Whether or not "one of ordinary skill in the art would be capable of making" a decision is not the obviousness standard. Applicants refer the Examiner to Winner International Royalty Corp. v. Wong, 53 USPQ2d 1580, 1587 (Fed. Cir. 2000). In that case, the Federal Circuit said that "trade-offs often concern what is feasible, not what is, on balance, desirable". To paraphrase the Examiner, "one of ordinary skill in the art would find it feasible to sacrifice quality for large time savings". In order for the substitution to be properly motivated, one of ordinary skill in the art would have had to recognize before sacrificing quality that such sacrifice would yield a greater benefit in time savings - the trade-off must be desirable. Following the Examiner's reasoning, an uncoated stent makes a coated stent obvious because omitting the coating step would save time. To be obvious, one of ordinary skill in the art must recognize beforehand that the cost-benefit calculus will provide a net overall benefit to making the substitution before one of ordinary skill in the art will be motivated to make the substitution.

If we go back in time to the time of filing the instant application, a skilled artisan would have known that omitting the step would produce inferior results. The skilled artisan would not have known whether the concommitant time savings would overcome the inferior quality. Therefore, at best, a skilled artisan would have been motivated to try omitting the step to determine whether, overall, that resulted in a better product. "Motivated to try" supports an obvious to try standard, not an obvious standard. In view of this, Applicants reproduce their previous discussion of Ofstead.

As a whole, Ofstead teaches that slowly removing solvent and then heat curing the resulting polymer results in a uniform coating. To get from Ofstead to Applicants' invention, one of ordinary skill in the art would have to reject slowly removing the solvent. "Air drying of the coating before heat treatment **for a period of time greater than 3 hours is preferred.**"[11] Ofstead teaches that the duration of the air drying has a pre-

[11] Ofstead, Col. 5, line 28.

ferred range, not that air drying is unnecessary. In fact, Ofstead says in the next sentence that without air-drying an inferior coating forms.

The Examiner cites case law to support that it is obvious to skip a step if the step is unwanted or unneeded. But one of ordinary skill in the art is not apt to sacrifice coating quality without a concomitant benefit. Without some other benefit (the Examiner identifies time savings), one of ordinary skill would not be motivated to sacrifice coating quality unless they knew beforehand that the positive aspects from saving time would outweigh the negative aspects of inferior coating quality.

Also, following this reasoning, one of ordinary skill in the art would have expected inferior coatings to result from omitting the air-drying step. If that is the case, Applicants' production of acceptable coatings when omitting the step is unexpected.

Moreover, to get from Ofstead to Applicants' invention, one of ordinary skill in the art would have had to reject Ofstead's teachings regarding heat treatment time. Ofstead discloses a typical treatment of at minimum 15 minutes or nine hundred seconds. Ofstead as a whole teaches one of ordinary skill a ballpark figure around which he or she would have optimized. But Applicants' heating time is nine times shorter than Ofstead. To get from Ofstead's communicated times to those of Applicants would, once again, require one of ordinary skill in the art to reject Ofstead's reasonable teachings related to time. Ofstead does not suggest that a shorter time is reasonable. In fact, because Ofstead does not intentionally use its heat treatment to remove solvent, but rather to anneal the coating, Ofstead inherently requires longer rather than shorter heating times.

One of ordinary skill in the art sees Ofstead as follows. First, a polymer coating is applied to a medical device. Next, air-drying removes most of the solvent to avoid bubbles in the coating caused by rapid solvent vaporization upon exposing the coating to heat. Finally, the coating is heat treated long enough to anneal the polymer coating.

One of ordinary skill would not start with Ofstead if he or she were aiming at Applicants' process. At the heart of Applicants' process is using heat to rapidly drive off solvent by vaporizing it—the very thing Ofstead avoids.

Since one of ordinary skill in the art would not be motivated to make the changes necessary to Ofstead's process. Ofstead does not make these claims obvious.

Please remove this rejection.

Since the Examiner has not made out prima facie obviousness with this reference because the Examiner has not explained how this reference makes the parent claim(s) obvious, the current rejections of the dependent claims are moot. But Applicants do not acquiesce to the Examiner's position in the rejections of sub-groups of the dependent claims and reserve the right to deal with the specifics of the rejections in the future, if that becomes necessary.

The Examiner has rejected claims 5, 9-13, 17-18, 20, 26-27, 29, and 37-38 under 35 USC 103(a) based on a primary reference to Ding.

Ding does not teach the steps of providing a coating substance comprising a solvent, a polymer, and an active agent; atomizing the coating substance; and spraying the coating substance onto an implantable medical device.

Neither of the secondary references cures this defect. Therefore, the Examiner has not made out a prima facie case of obviousness based on these references.

Please promptly remove this rejection under 35 USC 103(a).

Since the Examiner has not made out prima facie obviousness with this reference combination because the Examiner has not explained how this combination makes the parent claim(s) obvious, the current rejections of the dependent claims are moot. But Applicants do not acquiesce to the Examiner's position in the rejections of sub-groups of the dependent claims and reserve the right to deal with the specifics of the rejections in the future, if that becomes necessary.

The Examiner has rejected claims 1, 2, 24, 36, and 41-42 under 35 USC 103(a) based on a reference to Bouchier in view of Zhong.

Bouchier seals the coating chamber during application of the coating substance.[12] Bouchier states that the coating chamber is sealed to reduce solvent evaporation. In fact, any aeration of medical devices is done outside of the presence of the coating solvent.

Bouchier operates by bathing an implantable medical device in a warm solvent, which causes temporary changes in the polymeric medical device. If the spraying step of Zhong could be substituted into Bouchier's process, doing so would preclude the substituted process from operating with the same mode of action as described in Bouchier. Spray coating is designed to deposit the coating substance rather quickly with the solvent rather quickly evaporating. This is inconsistent with Bouchier's bathing, which is designed to treat implantable medical devices rather slowly with the solvent not evaporating in all. If the proposed combination changes the mode of action of either of the references, the combination is improper.

Additionally, Bouchier is interested in conserving solution, and Bouchier meets that goal by reducing the evaporation rate of the solvent by sealing the system. Zhong sprays its coating substance, which increases the evaporation rate of the solvent compared to Bouchier. To incorporate the spray coating methodology of Zhong, Bouchier would have to spray in an open system, which would negate Bouchier's goal of reducing evaporation of the solvent. Therefore, Bouchier teaches away from the spray coating methodology of Zhong. If a reference teaches away from its combination with the other cited references, the combination is improper.

For these reasons, the obviousness rejection based on Bouchier is a primary reference does not rise to the level of demonstrating a prima facie case of obviousness.

Please remove this obviousness rejection.

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[12] See figure 1, item 104; column 1, line 13; column 5, line 3; column 5, line 43; and column 10, lines 28-34.

Since the Examiner has not made out prima facie obviousness with this reference combination because the Examiner has not explained how this combination makes the parent claim(s) obvious, the current rejections of the dependent claims are moot. But Applicants do not acquiesce to the Examiner's position in the rejections of sub-groups of the dependent claims and reserve the right to deal with the specifics of the rejections in the future, if that becomes necessary.

The Examiner has rejected claims 1, 2, 24, 36, 41, and 42 under 35 USC 103(a) as being unpatentable over Bouchier in view of Berg

Bouchier seals the coating chamber during application of the coating substance.[13] Bouchier states that the coating chamber is sealed to reduce solvent evaporation. In fact, any aeration of medical devices is done outside of the presence of the coating solvent.

Bouchier operates by bathing an implantable medical device in a warm solvent, which causes temporary changes in the polymeric medical device. If the spraying step of Berg could be substituted into Bouchier's process, doing so would preclude the substituted process from operating with the same mode of action as described in Bouchier. Spray coating is designed to deposit the coating substance rather quickly with the solvent rather quickly evaporating. This is inconsistent with Bouchier's bathing, which is designed to treat implantable medical devices rather slowly with the solvent not evaporating in all. If the proposed combination changes the mode of action of either of the references, the combination is improper.

Additionally, Bouchier is interested in conserving solution, and Bouchier meets that goal by reducing the evaporation rate of the solvent by sealing the system. Berg sprays its coating substance, which increases the evaporation rate of the solvent compared to Bouchier. To incorporate the spray coating methodology of Berg, Bouchier would have to spray in an open system, which would negate Bouchier's goal of reducing evaporation of the solvent. Therefore, Bouchier teaches away the spray coating method-

[13] See figure 1, item 104; column 1, line 13; column 5, line 3; column 5, line 43; and column 10, lines 28-34.

ology of Berg. If a reference teaches away from its combination with the other cited references, the combination is improper.

Berg teaches an "extremely simple method" for coating a polymer and a drug onto a stent.[14] Berg demands a drug. Berg also wants a uniform coating.[15]

Procedure requires the Patent Office (Examiner) to set out a prima facie case of obviousness. This prima facie case consists of several elements including a motivation on the part of a skilled artisan to combine the references and a reasonable expectation of success on the part of a skilled artisan.

When Applicants filed the current application, an artisan looking at Berg could not reasonably expect success in supplying the heating step taught by Bouchier. First, the skilled artisan would not expect to maintain the simplicity of Berg by adding Bouchier's closed loop processor with multiple vessels and heating units requiring a microprocessor-based control system.

But most importantly, the skilled artisan could not have reasonably expected to achieve the increased solvent removal speed, without inadvertently degrading the more fragile drug. Moreover, increased solvent removal speed runs counter to the goals of Bouchier's methodology. There is no evidence of record that shows that a skilled artisan would have concluded that it would be worthwhile to heat Berg's stents.

Since a skilled artisan at the time the current invention was made could not reasonably have expected a successful marriage of Berg with the heating step of Bouchier, that combination does not make Applicants' invention obvious.

Please remove this rejection.

Since the Examiner has not made out prima facie obviousness with this reference combination because the Examiner has not explained how this combination makes the parent claim(s) obvious, the current rejections of the dependent claims are moot. But

[14] Berg, Col. 2, line 42.
[15] Col. 4, line 29.

Applicants do not acquiesce to the Examiner's position in the rejections of sub-groups of the dependent claims and reserve the right to deal with the specifics of the rejections in the future, if that becomes necessary.

The Examiner has rejected claims 5, 17-18, 20-21, and 43-44 under 35 USC 103(a) as being unpatentable over combination of references in which Bouchier serves as a primary reference.

Without repeating the discussion above, Bouchier's closed system cannot retain its mode of action if its immersion system is replaced with a spraying system. Therefore, Bouchier combined with any spraying reference is improper.

Please remove this rejection.

Since the Examiner has not made out prima facie obviousness with this reference combination because the Examiner has not explained how this combination makes the parent claim(s) obvious, the current rejections of the dependent claims are moot. But Applicants do not acquiesce to the Examiner's position in the rejections of sub-groups of the dependent claims and reserve the right to deal with the specifics of the rejections in the future, if that becomes necessary.

Since all claims are allowable, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,

Date: April 22, 2004

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